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PTO/SB/33 (11-08)
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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional): 16051-8US

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on _____

Signature _____

Typed or printed name _____

Application Number	Filed
10/661,415	09/12/2003

First Named Inventor: Andrew VAILLANT et al.

Art Unit	Examiner
1648	HURT, Sharon L

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- ☑ attorney or agent of record. Registration number 47,352.
- ☐ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____

/Christian Cawthorn/
Signature

Christian Cawthorn
Typed or printed name

514-847-4256
Telephone number

December 22, 2008
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☑ *Total of 3 forms are submitted.

File No. 16051-8US CC/DBB/

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Andrew VAILLANT et al.
Serial Number:	10/661,415
Filing Date:	September 12, 2003
For:	ANTIVIRAL OLIGONUCLEOTIDES TARGETING RSV
Art Unit:	1648
Examiner:	HURT, Sharon L.
Agent:	Cawthorn, Christian Direct Line: (514) 847-4256

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Assistant Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
U. S. A.

Sir:

Enclosed herewith is Form PTO/SB/33, i.e. a Pre-Appeal Brief Request for Review. Please consider the reasons set out below for which the review is being requested.

A Notice of Appeal is being filed concurrently.

REASONS:

Claims 1, 2, 14, 17, 18, 21, 23, 27, 28 and 30-32 have been rejected in the Official action issued August 6, 2008.

The Examiner stated that in the previous response submitted September 5, 2008, the limitation included in amended claims 1, 2 and 14 requires an additional search in the art and thus, the proposed amendment was not entered. In this regard, the Applicants believe that the amendment to claims 1, 2 and 14, further restricting that the oligonucleotides recited in the claims, does not represent new subject matter. Claim 1 has been amended in order to specifically encompass oligonucleotides having a sequence not comprising an immune system interacting CpG portion. In addition claim 2 has been amended to further

Assistant Commissioner for Patents

define that the oligonucleotides comprises only sequences selected from the group consisting of AA, CC, GG, TT, AC, CA, AG, GA, AT, TA, CT, TC, GT and TG which represent a subset or a selection of possible sequences disclosed in paragraph [0068] of the published application. Claim 14 has been amended in order to further define that the sequence of the encompassed oligonucleotides comprises only C, A or T nucleotides, which represents a selection of nucleotides disclosed in the published specifications at paragraph [0068].

It is submitted that claims 1, 2 and 14 were amended to include a limitation, not to broaden the scope of the claim. Furthermore, it is believed that the Examiner initially conducted a search on subject matter directed to a method for the prophylaxis or treatment of a RSV or parainfluenza virus infection in a subject, comprising administering at least one pharmacological acceptable oligonucleotide of at least 10 nucleotides in length and wherein the antiviral activity of said oligonucleotide occurs principally by a non-sequence complementary mode of action. The initial search conducted was broader and would include oligonucleotides currently claimed. Thus, the Applicants are of the opinion that by restricting the subject matter claimed in claims 1, 2 and 14 to oligonucleotides having a sequence not comprising any CpG portion interacting with the immune system; or a sequence comprising only C, A or T nucleotides; or only sequences selected from the group consisting of AA, CC, GG, TT, AC, CA, AG, GA, AT, TA, CT, TC, GT and TG, it should not require the Examiner to conduct an additional search in the art since the subject matter claimed in amended claims 1, 2 and 14 was already encompassed in the initial search conducted by the Examiner.

Despite the above, the only rejections of record are of claim 14 under 35 USC §112, second paragraph, as being indefinite, and of claims 1, 2, 14, 17, 18, 21, 23, 27, 28, and 30-32 under 35 U.S.C. 102(b) for allegedly being anticipated by Krieg et al.

Regarding the rejection of claim 14, the Examiner was of the opinion that the claim is drawn to a method wherein the oligonucleotide is a randomer oligonucleotide, which does not particularly point out or distinctly claim the invention since a single oligonucleotide can not be a randomer. In this regard, claim 14 has been amended to no longer define that the oligonucleotide is a randomer oligonucleotide in the response filed September 5, 2008. Thus,

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Applicants respectfully submit that the 35 U.S.C. §112, second paragraph rejection of claim 14 is improper, and request that it be withdrawn.

Regarding the rejection of claims 1, 2, 14, 17, 18, 21, 23, 27, 28, and 30-32 under 35 U.S.C. 102(b) for allegedly being anticipated by Krieg et al., we wish to resubmit that claims 3-13 and 15-42 have been cancelled. Further, the Krieg reference is only directed to a nucleic acid containing a specific nucleic acid sequence, namely a unmethylated cytosine-guanine dinucleotide (CpG) that activates the immune system via a sequence-dependent mechanism. Indeed, Krieg defines "immunostimulatory nucleic acid molecule" as:

"*a nucleic acid molecule, which contains an unmethylated cytosine, guanine dinucleotide sequence (i.e. "CpG DNA" or DNA containing a cytosine followed by guanosine and linked by a phosphate bond) and stimulates (e.g. has a mitogenic effect on, or induces or increases cytokine expression by) a vertebrate lymphocyte*" (Column 11, Lines 10-15).

In the specifications and the examples, Krieg et al. show that CpG containing oligonucleotides have immunostimulatory activity compared to non-CpG oligonucleotides (negative controls) having no or very low immunostimulatory activity (see for examples Fig. 1C, Fig. 2, Fig. 4B, Fig. 5, Fig. 7, Table 4, Table 8, Table 9, Column 19 lines 58-64, Column 21 lines 48-51, Column 22 lines 13-16, Column 24 lines 65-67, Column 25 lines 37-40, Column 27 lines 5-12, Column 28 lines 8-11, or Column 34 lines 36-40). In addition, Krieg et al. teaches the therapeutic uses of immunostimulatory nucleic acid molecules containing at least one unmethylated CpG dinucleotide (Column 33 line 11 to Column 35 line 20). Krieg et al. does not demonstrate, suggest or teach the activity or the use of non-CpG oligonucleotides for the treatment of viral infections.

Thus, in order to clearly distinguish the claims presently on file from the teaching found in Krieg et al., claim 1 has been amended in order to specifically encompass oligonucleotides having a sequence not comprising an immune system interacting CpG portion with the purpose of clearly distinguishing the subject matter recited in claim 1 from the teaching of Krieg et al.

In addition claim 2 has been amended to further define that the oligonucleotides comprises only sequences selected from the group consisting of AA, CC,

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GG, TT, AC, CA, AG, GA, AT, TA, CT, TC, GT and TG which represent a selection of possible sequences disclosed in paragraph [0068] of the published application that do not have a CpG portion.

Finally, claim 14 has been amended in order to further define that the sequence of the oligonucleotides comprises only C, A or T nucleotides, which represents a selection of nucleotides disclosed in the publish specifications at paragraph [0068] that do not have a CpG portion.

Applicants submit that they are well aware that in order for an invention to be patentable, it must be new as defined in the patent law, which provides that an invention cannot be patented if: "(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent," or "(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country more than one year prior to the application for patent in the United States..."

Thus, by specifying that the oligonucleotides have a sequence not comprising any CpG portion interacting with immune system; or a sequence comprising only C, A or T nucleotides; or only sequences selected from the group consisting of AA, CC, GG, TT, AC, CA, AG, GA, AT, TA, CT, TC, GT and TG, applicants are claiming subject matter which is not only supported and/or deduced from the present application, but that is believed to be new and inventive.

It is believed that the 35 U.S.C. §102(b) rejection of the claims for allegedly being anticipated by Krieg et al. is improper, and withdrawal is respectfully requested.

It is submitted, therefore, that the claims are in condition for allowance, and prompt and favorable action in the form of a Notice of Allowance is earnestly solicited.

Assistant Commissioner for Patents

Respectfully submitted,

Date: December 22, 2008

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Petition for extension of time
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